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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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5/5/96, 11/4 04/28/99 VAN DUSEN

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RM12/1256

EXAMINER

WILDER, C.

ART UNIT

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13

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/445,174

Applicant(s)

VAN OMMEN et al.

Examiner

CB Wilder

Group Art Unit

1655

☒ Responsive to communication(s) filed on Oct 20, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-14 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-14 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) for EP 97201700.8, filed June 4, 1997. The certified copy has been filed in the instant Application.

### ***CRF***

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

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4. Claims 1-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 1-11 are confusing at "a means" because a means is not properly defined in the specification and one of ordinary skill in the art would not recognize the scope of the claimed invention..

(b) Claims 6-12 are confusing at "anyone" because of improper claim format.

(c) Claims 7-13 are confusing at "major part" because the term "major part" in claim is a relative term which renders the claim indefinite. The term "major part" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(d) Claim 8 lacks proper antecedent basis for "nucleotides 1396-1662" because it is unclear to which numbering system the nucleotides are referring to or to what nucleic acid sequence. Clarification is required.

(e) Claim 14 is confusing at "other means" because said "other means" have not been defined in the specification or claims and it cannot be determined what Applicant is making reference to.

(d) Claim 14 is confusing at "is capable of" because it cannot not be determined whether "capable of" is a property of the probe or of the said "other means". It is suggested changing "is capable of distinguishing" to "which distinguishes".

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(f) Claim 14 lacks proper antecedent basis for “identifying the hybridization product” because the definition the hybridization conditions have not been identified and the prior steps do not indicate that hybridization has occur. Furthermore, the definition of “possible” is unclear in the context of the claim language.

***Claim Rejections - 35 USC § 102(b)***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1-3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Skolnick et al. (EP 0 699 754 A1, March 1996). Claim 1 is drawn to a diagnostic test kit for detecting the presence of or predisposition for breast cancer, whereby a means is provided for detecting a deletion of a stretch of nucleotides from a BRCA1 gene in a sample. Skolnick et al. teach a method and kit for detecting predisposition to breast and ovarian cancers, wherein the diagnostic techniques (bottom of page 18 to page 19, lines 1-6) includes detection of mutational events of the BRCA1 locus involving deletions, insertions, and point mutations within the coding sequences and non-coding sequences of the gene (page 5, lines 25-52).

Regarding claim 2, Skolnick et al. teach wherein the kit comprises at least one probe for hybridization (page 5, lines 25-27 and page 14, lines 54-57).

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Regarding claim 3, Skolnick et al. teach wherein the method and kit comprise the necessary elements for Southern Blotting (page 9, lines 44-46 and page 12, lines 3-4, see also page 40, lines 41-45).

Regarding claim 14, Skolnick et al. teaches wherein the presence in a sample of a nucleic acid derived from a BRCA1 gene having an alteration, wherein said alteration is a deletion, comprising contacting said sample with at least one probe capable of distinguishing between BRCA1 genes having the alteration and genes not having the alteration, allowing for hybridization between said probe and nucleic acid and identifying the hybridization product (pages 121 and 122, claims 1-9 and 22). Therefore, the claimed invention of claims 1-3 and 14 are anticipated by the reference of Skolnick et al.

***Claim Rejections - 35 USC § 102(e)***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

8. Claims 1-5, 11-14 rejected under 35 U.S.C. 102(e) as being anticipated by Swensen (6,150,514, effective filing date April 9, 1997). Regarding claim 1, Swensen teaches a method and diagnostic kit for detecting the presence of predisposition to breast and ovarian cancers, whereby a

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means is provided for detecting a deletion of a stretch of nucleotides from a BRCA1 gene in a sample (col. 6, lines 13-25).

Regarding claims 2 and 3, Swensen teaches a whereby the means comprises at least one probe for hybridization and the necessary elements for Southern blotting (col. 4, lines 53-58 and col. 9, subheading "Southern Blotting Analysis").

Regarding claim 4 and 5, Swensen teaches wherein the probe comprises sequences complementary to sequences on both sides of the deletion in the BRCA1 gene and wherein the deletion comprises one or more exons (Figure 2 and col. 4 beginning at line 58 to col. 5, lines 13).

Regarding claims 11, Swensen teaches whereby the deletion comprises a stretch of nucleotides between two ALU-elements (see Abstract and Figure 2).

Regarding claims 12 and 13, Swensen teaches probes for use in a diagnostic kit comprising a nucleic acid sequence which is a fusion of two ALU elements of the BRCA1 gene (col. 3, lines 40-50 and Example 1).

Regarding claim 14, Swensen teaches a method for determining the presence in a sample of a nucleic acid derived from a BRCA1 gene having a deletion of a stretch of nucleotides, comprising contacting said sample with at least one probe capable of distinguishing between BRCA1 genes having said deletion and genes not having said deletion, allowing for possible hybridization between said probe and said nucleic acid and identifying the hybridization product (bottom of col. 2 bridging top of col. 3, lines 1-4 and col. 6, lines 13-26 and 49-63). Therefore the claimed invention of claims 1-5 and 11-14 are anticipated by the reference of Swensen.

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*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 4-6, and 11-13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Puget et al. (Cancer Research, March 1997) in view of Ahern (The Scientist, July 1995). Claim 1 is drawn to a diagnostic test kit for detecting the presence of or predisposition for breast cancer, whereby a means is provided for detecting a deletion of a stretch of nucleotides from a BRCA1 gene in a sample. Puget et al. teach a method for detecting the presence or predisposition for breast cancer whereby a means is provided for detecting a deletion of a stretch of nucleotides from a BRCA1 gene in a sample (see Abstract and page 830, last paragraph of col. 1 and col. 2, lines 13-19). The method for detecting predisposition to breast cancer of Puget et al. differs from that of the claimed invention in that Puget et al. do not teach wherein the method is in the form of a kit. In a scientific article, Ahern teaches the advantages of using a kit. Ahern states that a kit provides convenience, time management and ease of practicing to the investigator (page 4, second-fourth paragraphs). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of detecting predisposition of breast cancer as taught by Puget et al. in the form of a kit for the overall convenience and ease of practicing as taught by Ahern.



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Regarding claims 2, 4, 12 and 13, Puget et al. teach a method for detecting the presence of predisposition for breast cancer whereby a means is provided for detecting a deletion of a stretch of nucleotides from a BRCA1 gene in a sample wherein the method provides oligonucleotides primers complementary to regions on both sides of the deletion (page 829, Figure 2). Puget et al. further teaches wherein Southern blotting techniques are performed such that the breakpoint junction is identified between repetitive elements of the ALU family (page 830, col. 2, lines 13-28). Puget et al. do not expressly teach wherein probes for hybridization are provided in the kit comprising a fusion product of two sequences adjacent to the site of a deletion of a stretch of nucleotides. However, the claimed probes are inherent in the Southern blotting method which identified the breakpoint junction between the ALU elements. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide said probe(s) in the form of a kit for the convenience and ease of analyzing mutations predisposing to breast cancer as taught by Puget et al. (see Abstract).

Regarding claim 5, Puget et al. teach wherein the method detects a deletion comprising an exon of the BRCA1 gene (page 829, Figure 2).

Regarding claim 6, Puget et al. teach wherein the deletion comprises a frameshift (col. 1, third line from bottom of paragraph two).

Regarding claim 11, Puget et al. teach wherein the deletion comprises a deletion of a stretch of nucleotides between two ALU-elements (page 830, col. 2, lines 13-28).

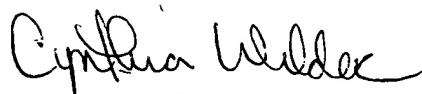
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*Conclusion*

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.



Cynthia B. Wilder, Ph.D.

December 4, 2000



W. Gary Jones  
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12/4/00